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VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

Ref: Customs Entry No. 826-0078004-1
Fresh and Frozen Scallops

WARNING LETTER

FLA-01-56

May 9, 2001

Knox Grant, President
Atlantic Littleneck Clam Farm
2107 Folly Road
Charleston, South Carolina 29412-9542

Dear Mr. Grant:

The Food and Drug Administration (FDA) was prepared to examine a shipment of fresh and frozen scallops offered for entry into the United States by your firm on March 23, 2001, under the above referenced entry number. On March 30, 2001, FDA received notification from America's Custom Broker that the entry had been shipped. As of this date, Atlantic Littleneck Clam Farm has not made the shipment available for FDA examination.

Title 21, Code of Federal Regulations (21 CFR), Section 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Notice of Release" from FDA. Since the product was not held intact, we have requested the U. S. Customs Service (Customs) to order redelivery of the fresh and frozen scallops that have been distributed without a release from FDA (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation. Your response should include an explanation of each step being taken to prevent the recurrence of the violation. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

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Your written reply should be addressed to the Food and Drug Administration, Attention:
Magda M. Karlsen, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,



for Emma R. Singleton
Director, Florida District

cc: Thomas Winkowski
Port Director
U. S. Customs Service
P. O. Box 02-580
Miami, Florida 33102-5280

America's Custom Brokers, Inc.
2050 N.W. 70th Avenue
Miami, Florida 33122